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| 09/367,013 | 08/05/1999 | DEBORAH KNUTZON | CGAB-210-USA | 3773 |

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EXAMINER

NASHED, NASHAAT T

| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 06/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/367,013

Applicant(s)
Knutzon et al.

Examiner
Nashaat T. Nashed

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 23, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 189-284 is/are pending in the application.
- 4a) Of the above, claim(s) 189-214 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 215-284 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

The application has been amended as requested in the communication filed April 23, 2002. Accordingly, claims 65-160 and 187 have been canceled and new claims 189-284 have been entered.

New claims 189-214 and 215-284 are drawn to two independent methods which do not relate to a single inventive concept under PCT Rule 13.1. The methods of claims 189-214 are drawn to a method of making a transformed host cell using the nucleic acid sequence of SEQ ID NO: 1. Thus, the special technical feature for the invention of claims 189-214 is the nucleic acid of SEQ ID NO: 1 which has been previously patented in one of the parent applications. In contrast, the method of claims 215-284 are drawn to a method of making oil, presumably, enriched in stearidonic acid. The special technical feature for the method of claims 215-284 are the transformed host cell produced by the method of claims 189-214. Thus, the inventions of claims 189-214 and 215-284 do not share a common inventive concept under PCT Rule 13.1. One may argue that the two methods are related to a single inventive concept which is the nucleic acid sequence of SEQ ID NO: 1. Applicants are reminded that the nucleic acid sequence of SEQ ID NO: 1 was known at the time of invention and the two methods represent two different uses of otherwise known chemical compound. It should be noted that the application had been restricted in paper number 12, and applicants have elected the invention of Group I drawn to method of making fatty acids without traverse, and elected the species of stearidonic acid without traverse for initial prosecution. Thus, claims 189-214 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 215-284 are under consideration.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The following phrase are not found in the specification, and therefore, the claims should be deleted or amended to remove the new subject matter in the claims: (i) "deletion mutant of the nucleic acid sequence of SEQ ID NO: 1" in claims 235 and 245; (ii) "at least 60% homology to SEQ ID NO: 2" in claim 265; and (iii) "nucleic acid that hybridizes to the complement of the sequence depicted in SEQ ID NO: 1" in claim 275.

The use of the trademark ISOMIL[®], SIMILAC[®], and OXEPA[™] have been noted in this application, see pages 70-74 and 92. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicants have not responded to the above objection to the specification.

Claims 215-284 are objected to because they are dependent on nonelected subject matter. For examination purposes only, all the embodiment of the parent claims are included in the examined claims. Appropriate correction is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 215-284 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-10 and 15 of U.S. Patent No. 6,136,574 ('574) for the reasons set forth in the prior Office action, paper number 15 in rejecting canceled claims 65, 66, 94, 99, 100, and 189.

Claims 215-284 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,075,183 ('183) for the reasons set forth in the prior Office action, paper number 15 in rejecting canceled claims 65, 66, 94, 99, 100, and 189.

Claims 215-284 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-20 and 26-30 of U.S. Patent

No. 5,968, 809 ('809) for the reasons set forth in the prior Office action, paper number 15 in rejecting canceled claims 65, 66, 94, 99, 100, and 189.

In response to the above rejections, applicant contended that the cancellation of claims 65, 66, 94, 99, 100, and 187 have been canceled which render these rejections moot, and otherwise traversed. No reasons or argument for the traversal is given.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 225-254 and 265-284 rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to methods of a lipid fraction enriched in stearidonic acid using yeast transformed with the nucleic acid sequences encoding Δ -6-desaturase of SEQ ID NO: 2 including SEQ ID NO: 1 from *Mortierella alpina*. The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims. The claims are broader than the enablement provided by the disclosure with regard to all nucleic acid sequences having 50% homology to SEQ ID NO: 1, any deletion mutants to SEQ ID NO: 1, or nay nucleic acid encoding a polypeptide having 60% homology to SEQ ID NO: 2 wherein the polypeptide encoded by said nucleic acid has the desaturase activity of SEQ ID NO: 2. Factors to be considered in determining whether undue experimentation is required, are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses a general method of obtaining an oil with modified fatty acid composition using any microbial cell transformed with any nucleic acid having 50% sequence homology to, hybridizes under any set of conditions to or deletion mutation of SEQ ID NO: 1, and encoding any polypeptide having 60% sequence homology to SEQ ID NO: 2 which include nucleic acid encoding insertion, deletion, substitution and combination thereof mutants obtained from any natural or man-made source. The specification provides guidance and examples in the form of an assay to isolate and characterize the nucleic acid encoding Δ -6-desaturase of SEQ ID NO: 2 and

Δ -12-desaturase of SEQ ID NO: 4 from *Mortierella alpina* and their use in obtaining unsaturated fatty acid from a culture of microorganism (see examples 1-8) and isolation and determining the amount of each unsaturated fatty acid in a lipid fraction. While molecular biological techniques and genetic manipulation to make the transformed microbial cell are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological source of all variants nucleic acids that encompassed by the claims, the amino acids to be deleted, substituted, and inserted without comprising the enzymatic activity, methods of re-designing up to 40% of the amino acid residues of the protein of SEQ ID NO: 2 while maintaining its enzymatic activity, and a method of changing the composition of an oil to contain enhanced amount of any fatty acid is lacking. Thus, searching for a nucleic acid sequence or its multiple mutants encoding a polypeptide having the enzymatic activity of SEQ ID NO: 2. The amount of experimentation to identify a nucleic acid encoding a polypeptide having 60% sequence homology to SEQ ID NO: 2 or a nucleic acid having 50% sequence homology to SEQ ID NO: 1 and having the desaturase activity of SEQ ID NO: 2 is enormous. Since routine experimentation in the art does not include screening vast numbers of genomic, cDNA or manmade DNA libraries for the desaturase activity of SEQ ID NO: 2 and develop a method to obtain an oil that has an altered composition of fatty acid, where the expectation of obtaining the desired nucleic acid and modified fatty acid composition is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the biological source, the amino acid residues which can be deleted, inserted, or substituted without altering the desaturase activity of SEQ ID NO: 2, the dimensional structure of SEQ ID NO: 2 and a method of re-designing up to 40% of the protein while maintaining its desaturase function. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claims 215-284 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) the phrase "microbial cell produced according to the method of claim" in claims 215, 225, 235, 245, 255, 265, and 275 is render the claim indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. None of the methods in the non-elected claim produces a transformed host cell. The end result of the methods of claims 189, 193, 201, 202, 205, 208, and 214 are culture soups containing fatty acid composition, presumably, different from that produced by the wild type-microbial cells
- (b) the phrase "altering fatty acid profile" in claims 215, 225, 235, 245, 255, 265, and 275 is render the claim indefinite. The phrase is not define by the claim

or the specification, and one of ordinary skill in the art would not know in which way the fatty acid profile is altered. Replacing the phrase with "an increased amount stearidonic acid from a transformed microorganism relative to that produced by wild-type microorganism" would lead to vacating these rejections.

- (c) the methods of claim 215, 225, 235, 245, 255, 265, and 275 are incomplete because they are omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: (a) culturing a host microbial cell transformed with a nucleic acid comprising the nucleic acid sequence encoding the desaturase of SEQ ID NO: 2; (b) inducing the cell to produce the desaturase of SEQ ID NO: 2 in sufficient quantity to produce stearidonic acid; and (c) isolating the oil containing the stearidonic acid from the cell culture.
- (d) the phrase "hybridizes to the complement of the sequence depicted in SEQ ID NO: 1" in claim 275 renders the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Since nucleic acid are no to hybridize to any other nucleic acid sequence under different conditions, the nucleic acid sequence of SEQ ID NO: 1 is expected to hybridize to any nucleic acid sequence. Thus, the claim is considered indefinite. Since the specification does not contain any specific hybridization conditions, the claim can't be amended to obviate this rejection.
- (e) Claims 225-234, 236-244, 246-254, 256-264, 266-274, and 276-284 are included in this rejection and do not cure the deficiencies of the claims from which they depend.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Serial Number: 09/367,013
Art Unit: 1652

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Nashaat T. Nashed, Ph. D.
Primary Examiner